

PATENT COOPERATION TREATY

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From the INTERNATIONAL SEARCHING AUTHORITY

PCT

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|---|---|
| To: G.E. EHRLICH (1995) LTD. 11 Menachem Begin Street 52521 Ramat Gan ISRAEL |  25 SEP 2008 FILE No. 43727 G.E. EHRLICH (1995) LTD. |
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**INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE**
(PCT Article 17(3)(a) and Rule 40.1 and 40.2(e))

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| Applicant's or agent's file reference 43727 | Date of mailing (day/month/year) 01/09/2008 |
| International application No. PCT/IL2008/000406 | PAYMENT DUE within ONE MONTH from the above date of mailing International filing date (day/month/year) 24/03/2008 |
| Applicant DUNE MEDICAL DEVICES LTD. | |

1. This International Searching Authority

- (i) considers that there are 4 (number of) inventions claimed in the international application covered by the claims indicated on an extra sheet;
- (ii) therefore considers that **the international application does not comply with the requirements of unity of invention** (Rules 13.1, 13.2 and 13.3) for the reasons indicated on an extra sheet;
- (iii) has carried out a partial international search (see Annex) will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:
see extra sheet
- (iv) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid.

2. Consequently, the applicant is hereby invited to pay, within the time limit indicated above, the amount indicated below:

EUR 1.700,00 x 3 = EUR 5.100
 Fee per additional invention number of additional inventions currency/total amount of additional fees

3. The applicant is informed that, according to Rule 40.2(c), the payment of any additional fee may be made under protest, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive, where applicable, subject to the payment of a protest fee. Where the applicant pays additional fees under protest, the applicant is hereby invited, within the time limit indicated above, to pay a protest fee (Rule 40.2(e)) in the amount of EUR 750,00 (currency/amount)

Where the applicant has not, within the time limit indicated above, paid the required protest fee, the protest will be considered not to have been made and the International Searching Authority will so declare.

4. Claim(s) Nos. _____ have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

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| Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016 | Authorized officer Hans Van Brummelen |
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This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5,9-13

Tissue characterization device with (adjustable) angle between handle and sensor

1.1. claim: 5

Vacuum system for better tissue contact

1.2. claims: 10,12,13

Particular kinds of sensors

2. claims: 6,14-26

Lighting means for improved visibility in the dark

3. claims: 7,27-39

Device for marking diseased tissue

4. claims: 8,40-52

Transparent window to avoid view obstruction.

Please note that all inventions mentioned under item 1, although not necessarily linked by a common inventive concept, could be searched without effort justifying an additional fee.

Reference is made to the following document:

D1: US 6 093 150 A

Document D1 discloses all the features of claim 1 (the references in parentheses refer to this document):

An ergonomic (column 10, lines 6-8) device (100) for intraoperative tissue characterization, comprising:
a body, which comprises:
proximal (7) and distal (9) portions, with respect to the tissue, as it is characterized;
a gripping handle (9), at the distal portion; and
a sensor head (6), at the proximal portion, the sensor head comprising at least one sensor (6) for tissue characterization,
wherein the gripping handle and the sensor head are arranged at an angle a, wherein in absolute value, a > 10 degrees (Fig. 2b).

Document D1 also discloses all the additional features of the following

claims dependent on claim 1:

- Claim 2: see column 8, lines 22-36 and Figs. 4a-b.
- Claim 3: see column 8, lines 35-56 and Figs. 2a-4b.
- Claim 4: see column 7, lines 4-7 and column 8, lines 35-56.
- Claim 9: see column 6, lines 28-43.
- Claim 11: see column 6, lines 38-41 and Figs. 4a-4d.

Furthermore, document D1 discloses the following features of the other independent claims 14, 27 and 40:

An ergonomic (column 10, lines 6-8) device (100) for intraoperative tissue characterization, comprising:

a body, which comprises:
proximal (7) and distal (9) portions, with respect to the tissue,
as it is characterized;
a gripping handle (9), at the distal portion; and
a sensor head (6), at the proximal portion, the sensor head
comprising at least one sensor (6) for tissue characterization.

Therefore, regarding the remaining dependent claims of claim 1 and the other independent claims 14, 27 and 40, the following special technical features (STF) can be recognized (Rule 13.2 PCT):

- Claim 5: sensor head includes vacuum system;
- Claims 6 and 14: sensor head includes light fixture;
- Claims 7 and 27: sensor head includes marking module;
- Claims 8 and 40: sensor head includes transparent frame;
- Claim 10: sensor of a particular type;
- Claim 12: at least two different types of sensors;
- Claim 13: sensors of particular types.

The technical problems solved by these special technical features can be regarded as follows:

- Claim 5: Improved tissue contact;
- Claims 6 and 14: Improved visibility of tissue being observed in the dark;
- Claims 7 and 27: Improved recognition of diseased tissue;
- Claims 8 and 40: Avoiding view obstruction by the device;
- Claims 10, 12 and 13: Performing measurements of a certain type.

Hence, the following special technical features can be regarded as corresponding STF in the sense of Rule 13.2 PCT:

- 1) Claim 5: Vacuum system;
- 2) Claims 6 and 14: Lighting means for the tissue;
- 3) Claims 7 and 27: Marking device;
- 4) Claims 8 and 40: Transparent frame around the sensor head;
- 5) Claims 10, 12 and 13: Particular types of sensor(s).

INVITATION TO PAY ADDITIONAL FEES

International application No.

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In conclusion, the groups of claims are not linked by common or corresponding special technical features and define 5 different inventions not linked by a single general inventive concept. The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

Although group 5) relates to a different invention, it can be searched without further effort justifying additional search fees.

Annex to Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No

PCT/IL2008/000406

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:

see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|---|-----------------------|
| X | US 6 093 150 A (CHANDLER PAUL E [US] ET AL) 25 July 2000 (2000-07-25) column 6, line 56 - column 7, line 7 column 7, line 38 - column 8, line 56 column 9, line 66 - column 10, line 13 figures 1a-4d | 1-4,9,11 |
| Y | ----- | 5,10,12, 13 |
| X | US 2002/148277 A1 (UMEDA MANABU [JP]) 17 October 2002 (2002-10-17) paragraph [0062] - paragraph [0070] figures 1,4,5 | 1,2,9,11 |
| Y | ----- US 2005/119648 A1 (SWANSON DAVID K [US]) 2 June 2005 (2005-06-02) paragraphs [0079], [0088] paragraph [0091] - paragraph [0099] paragraphs [0120], [0129] figures 1,5-7 | 5,10,12, 13 |
| A | ----- US 2005/159689 A1 (OLSON CHUCK [US]) 21 July 2005 (2005-07-21) paragraph [0013] - paragraph [0018] figure 1 | 1-5,9-13 |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Patent Family Annex

Information on patent family members

International Application No

PCT/IL2008/000406

| Patent document cited in search report | Publication date | Patent family member(s) | | Publication date |
|--|------------------|---|--|--|
| US 6093150 | A 25-07-2000 | NONE | | |
| US 2002148277 | A1 17-10-2002 | CN 1380040 A JP 2002306486 A KR 20020079554 A | | 20-11-2002 22-10-2002 19-10-2002 |
| US 2005119648 | A1 02-06-2005 | WO 2005060828 A1 | | 07-07-2005 |
| US 2005159689 | A1 21-07-2005 | NONE | | |